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Nos. 80-2182, 81-11

In the Supreme Court of the United States

October Term, 1981

DARBY DRUG CO., INC., INWOOD LABORATORIES, INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,
Petitioners,

vs.

IVES LABORATORIES, INC.,
Respondent.

BRIEF OF AMICUS CURIAE AMERICAN ACADEMY OF FAMILY PHYSICIANS IN SUPPORT OF RESPONDENT

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DARBY DRUG CO., INC., INWOOD LABORATORIES, INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,
Petitioners,

vs.

IVES LABORATORIES, INC.,
Respondent.

BRIEF OF AMICUS CURIAE AMERICAN ACADEMY OF FAMILY PHYSICIANS IN SUPPORT OF RESPONDENT

INTEREST OF THE AMICUS CURIAE

The question before the Court is whether manufacturers and distributors of prescription drugs are liable for contributory infringement of a registered trademark when they package and distribute a generic drug identical in appearance to the brand name drug for which theirs is generic. Petitioners' briefs present to the Court the position of the generic drug manufacturers and distributors. Respondent's brief presents to the Court the position of the brand name drug manufacturer. One very important position has yet to be presented to the Court - that of the

physician whose task is to provide medical care to his patients.

Because of the complex and technical bases on which prescribing decisions are made, patients as such do not possess the medical knowledge to assess and present their own true needs in this area. The medical needs of the patients are the business of the medical profession. Accordingly, the most significant spokesman for the needs of the patient relevant to the inquiry before the Court is the patient's own physician.

The American Academy of Family Physicians (hereinafter called the "Academy") is the professional society of physicians specializing in the field of family medicine. It is the largest medical specialty society in the world. As of October 31, 1981, the Academy had 51,147 members.

One purpose for which the Academy was organized is to ensure that the people of America receive excellence in health care. In its most recent fiscal year ended May 31, 1981, Academy members contributed $3,132,778 in dues payments to the Academy to assist in the furtherance of overall goals of their profession. From these funds and other sources developed by the Academy, the Academy in that year expended a total of $11,400,620 in various projects designed to promote and maintain high standards of family and general practice of medicine and surgery; to encourage and assist young men and women in preparing, qualifying and establishing themselves in family and general practice; to preserve the right of family physicians to engage in medical and surgical procedures for which they are qualified by training and experience; to assist in providing post-graduate study courses for family physicians and to encourage and assist practicing physicians to participate in such training; to promote the general betterment of public health and to preserve to patients their

right of free choice of their physician; and to engage in responsible public advocacy in connection with issues relating to the provision of medical care for the public.

The Academy is a national body with 54 chartered constituent chapters in all 50 states, the District of Columbia, Puerto Rico, the Virgin Islands and the uniformed services. The Academy is organized structurally to provide representative government at the national level for all its members. To this end, each chartered constituent chapter selects two representatives to a Congress of Delegates, which meets annually and which is the supreme authority within the Academy for determining the Academy's position on any issue. The Congress of Delegates selects members of a Board of Directors which has authority to govern the Academy and to determine its affairs between meetings of the full Congress. Accordingly, policy positions of the Academy, of which some are hereinafter quoted, constitute the collective determination of the full national membership of the Academy as expressed through its representatives at its Congress of Delegates.

This brief for this *Amicus Curiae* discusses the following points in support of Respondent's position:

1. The need of the physician, in treating a patient, to be able to know in appropriate circumstances the specific products, including the brand of medications, his patient is actually receiving in response to the prescriptions issued by the physician.

2. The patient's right to know and to be able to determine whether his prescription has been filled with a brand name drug or its generic substitute and, where the latter is appropriate, whether he has received the benefits of any cost savings.

SUMMARY OF THE ARGUMENT

To provide effective medical care for a patient, a physician must have the right to prescribe specific medicines for his patient and where appropriate to restrict the medicines dispensed by a pharmacist to particular prescribed brands of medications. Such right of the physician to control what is dispensed under his prescriptions has been acknowledged even in laws otherwise permitting a pharmacist to make substitutions in prescriptions where the physician has not exercised his right to restrict the pharmacist to particular brands.

Unauthorized substitutions in prescriptions, intentional or not, subvert the physician's medical care of his patient. Marketing practices which permit or encourage the possibility of confusion between different brands of a given medication create conditions in which unauthorized substitutions may be undetected, because a patient will not be put on his inquiry to determine what he has received and will accordingly feel no occasion to raise any questions with his physician to ascertain what the patient has received. Unauthorized substitutions which are not known to the patient or his doctor could endanger the health of the patient because the doctor may be led to improper diagnoses either of the patient's conditions or of the efficacy of a particular medication in treating that condition.

Laws permitting authorized substitutions are intended to secure cost savings for patients. When a prescription is filled by substitution, whether such substitution is authorized or not, if the patient has no knowledge of the substitution, he may not know he is entitled to cost benefits and may therefore not receive the cost savings the laws intended for him. The possibility that a substitution may be made without the patient's knowledge, even though

authorized by law, is heightened by trade or marketing practices which are intended to make different products similar in appearance and which accordingly provide a patient no visual perception that a substitution has been made.

Requiring different brands of a medication to be different in appearance eliminates at least one set of possibilities of confusion both in the medical care of a patient and in the patient's awareness of his right to financial savings where appropriate. Requiring such differences in appearances will aid physicians in providing quality medical care without countervailing detriments to physician convenience and without significant cost to manufacturers.

ARGUMENT

I. Optimal Medical Treatment of a Patient Requires That the Physician Be Able to Direct the Medications to Be Dispensed to the Patient, and Practices Which Permit or Encourage Substitutions in Prescriptions Without the Knowledge of Either the Patient or His Physician Are Not in the Best Interests of Quality Medical Care and May Endanger the Patient's Health.

Virtually every drug which has been promoted under a registered trademark in fact has three different names:

1. The chemical name which describes the chemical structure or composition of the drug.
2. The generic name which describes the chemical class to which the drug belongs.

3. The brand name which is the registered trademark of the manufacturer and which describes the source of the drug.[1]

The brand name drug is usually more expensive than the generic drug of the same chemical class. The brand name drug manufacturers have invested great sums in clinical research and development, in the drug approval process, and in marketing of the drug. The generic drug manufacturer does little, if any, pharmaceutical product research and does not incur costs associated with introducing a new product.

Virtually all states and the District of Columbia have enacted Generic Drug Substitution laws which permit the pharmacist to substitute, under certain specified conditions, a generic drug for a brand name drug which has been prescribed. The general purpose of making the drug available in its generic form is to permit the consumer to receive the lowest cost form of the drug. In the ideal situation, cost savings realized by substituting a generic drug for a brand name drug will be passed on to the consumer.

The prescription drug market is very different from a classic free market. Most consumers of prescription drugs lack the knowledge to deal effectively with the supplier of drugs. The consumer receives his drug packaged in an anonymous bottle bearing only the pharmacist's label. He is unable to determine whether the proper drug is being dispensed and must rely on the ability and the honesty of his pharmacist.[2]

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1. Warner, "Consumer Protection and Prescription Drugs: The Generic Drug Substitution Laws," 67 Kentucky Law Journal 384, 388 (1978-1979).

2. See Warner, "Consumer Protection and Prescription Drugs: The Generic Drug Substitution Laws," 67 Kentucky Law Journal 384 (1978-1979) which describes some of the drug legislation that has been enacted to protect the consumer in this situation.

Courts have recognized that prescribing drugs is a specialized task based upon the sophisticated diagnostic skills of a physician. In deciding which drug to prescribe to the patient, the physician must consider the nature of the ailment and the identity of his patient. If more than one type of drug is available to treat the ailment, the physician must select the drug which he believes is most appropriate and in which he has the most confidence based upon his experience.[3]

A brand name drug and its generic substitute may be chemically equivalent without being therapeutically equivalent. *U.S. v. Premo Pharmaceutical Laboratories, Inc.*, 511 F.Supp. 958, 963-965 (D.N.J. 1981). The Drug Bioequivalence Study Panel, charged by the Office of Technology Assessment (an agency of which the Board of Directors consisted of Senators and Representatives and the Chairman of which in 1974 was Senator Edward M. Kennedy) "to examine the relationships between the chemical and therapeutic equivalence of drug products," stated in its report to Congress dated July 15, 1974:

> "It was clear to us from the outset that certain chemically equivalent drug products have produced clinically important and measurable differences in therapeutic effect and that these differences were the result of differences in bioavailability."[4]

Each finished dosage form is composed of active and inert ingredients that may undergo a complicated manufacturing process. Two drugs that contain identical active chemical ingredients may not have the same effectiveness

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3. *Hoffman La Roche, Inc. v. Premo Pharmaceutical Laboratories, Inc.*, 210 USPQ 374, 383 (D.N.J. 1980).

4. *Drug Bioequivalence*, A Report of the Office of Technology Assessment Drug Bioequivalence Study Panel (U.S. Govt. Printing Office, 1974), p. 5.

in treating an ailment because of small differences in their inert ingredients or in manufacturing techniques. *U.S. v. Premo Pharmaceutical Laboratories, Inc.*, 511 F.Supp. 958, 963-965 (D.N.J. 1981).

For example, the dissolution rate of the brand name drug and its generic substitute may be different so that one drug may dissolve and begin working more quickly than the other. Such differences in the dissolution rate could be critical in situations where the speed of the drug is important. *U.S. v. Premo Pharmaceutical Laboratories, Inc.*, 511 F.Supp. 958, 982-985 (D.N.J. 1981). Sometimes a physician will prescribe a particular brand name drug because it has a special feature which the chemically equivalent generic drug does not have or because the carrying agent of the brand name or generic drug is not compatible with the other drugs that the patient is taking.[5]

At least as early as 1967 the Academy's Congress of Delegates adopted a formal policy position for the Academy which incorporated significant recognition of the need for a physician to have the freedom of choice to prescribe a generic drug or a brand name drug, as the physician might determine most appropriate for the circumstances.[6]

Consistent with all of the foregoing, the Academy's Congress of Delegates adopted the following formal policy at its session in 1970:

> "The Academy contends chemical equivalency does not equate with therapeutic equivalency: that the effectiveness and method of use of drug products is determined by clinical impressions of the medical pro-

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5. Willig, "The Prosubstitution Trend in Modern Pharmacy Law," 6:1 Journal of Law Reform 1, 19-21 (Fall 1972).

6. American Academy of Family Physicians, *1981-1982 Ready Reference Guide, Academy Policy on Key Health Issues* 16 (1981).

fession, based on their actual determination of what the drug product will do for their patients; and that the clinical training and experience of the physician has equipped him to be the most effective therapeutist in the patient's best interests. The Academy believes that, because the physician is responsible for total care of those patients who come under his supervision, the physician should determine the medical product to be prescribed for his patient and that the pharmacist should not be allowed to fill the prescription with a product not intended by the prescribing physician.[7]

The need for a physician to have control over the medication that his patient receives is acknowledged even in the most far-reaching of the various state statutes which have been adopted to encourage generic substitution of drugs. Even those statutes which in effect do not merely permit but require a pharmacist to make such generic substitutions whenever feasible retain the specific right for a physician to indicate on his prescription that the pharmacist must dispense only the specifically prescribed drug or, where so limited, the specifically prescribed brand of drug.[8]

Given the need in appropriate circumstances for the physician to have control over the brand of medicine he prescribes, combined with the fact that the patient receives the actual medicine not from his physician but from a pharmacist in a separate location, whatever conditions would assist a patient in detecting a substitution in his prescription will be to that patient's medical benefit. If safeguards can be devised to alert a patient visually to a sub-

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7. American Academy of Family Physicians, *1981-1982 Ready Reference Guide, Academy Policy on Key Health Issues* 14 (1981).

8. Warner, "Consumer Protection and Prescription Drugs: The Generic Drug Substitution Laws," 67 Kentucky Law Journal 384, 397 (1978-1979).

stitution, the patient can be on his inquiry to let his doctor know of such substitution.

Conversely, however, if the patient can be fooled by deceptively similar appearances of differing brands of medicines, then perforce the patient will never have occasion to raise any question with his doctor, and the physician will never know that the patient may be receiving a different brand of drug from that prescribed.

The use of differing colors on different products would at least make it more likely that a patient might notice an unauthorized substitution. However, apparently it is precisely the notice by a patient that the Petitioners' products are not those of the Respondent which the Petitioners fear and which the Petitioners are trying to avoid by the use of colors of identical shade and description with those of the Respondent's product.

With the patient's welfare at stake, and with the physician's need to have every possible assistance in treating the medical needs of his patient, and given the impossibility of scientific treatment if the patient receives, without the knowledge of the physician, a different brand of medicine when a specific brand has been prescribed, physicians can only be amazed that manufacturers of drugs would not affirmatively desire to differentiate their products for distinctive identification.

However, Petitioners contend that they need to use the same colors for their products as those used by the Respondent in order to compete commercially with the Respondent.

Perhaps the shortest and quickest answer is that the record herein shows at least one manufacturer has indeed found it possible to market the generic product at issue in this case in capsules of a different color from those of the

Respondent. *Ives Laboratories, Inc. v. Darby Drug Co.*, 638 F.2d 538, 545 (2nd Cir. 1981).

Even if so practical an answer were not available, the Academy would respectfully suggest that not even so vital a principle as free commercial competition is unlimited. Surely competition is not so sacred an idol that the physical welfare of patients must be sacrificed upon its altar.

Indeed, is it truly "competition" we are discussing, when the privilege sought is not the right to persuade a consumer to purchase a manufacturer's product in preference to that of his competitors, but rather a right to deceive the consumer into thinking it is the competitor's product he is buying? Certainly this type of "competition" has not been favored by the courts. As the Court in *SK&F Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3rd Cir. 1980), succinctly stated:

> ". . . Premo [argued] . . . that it could compete more effectively in the diuretic market if it could use the same maroon and white capsule color adopted by SKF for DYAZIDE. Probably it could compete better still if it could appropriate the same trade name. But neither appropriation has the look, sound, or feel of equity." *Id.* at 1067.

Clearly something is wrong with "competition" the goal of which is to deceive patients into thinking they are getting a product which they are not. Even more to the point so far as the Academy is concerned, such "competition" may be dangerous to the physical welfare of the patient: if the patient does not know he is getting a different brand of product from the one actually prescribed for him, the doctor may never know that the patient is not receiving the brand of medicine prescribed. The physician may therefore reach inaccurate decisions because the in-

formation provided to him is inaccurate. *U.S. v. Premo Pharmaceutical Laboratories, Inc.*, 511 F.Supp. 958, 985 (D.N.J. 1981).

Given the need of the physician to know and in appropriate cases to be able to control the brand of medicine dispensed to his patient, the conclusion of the opinion below provides an elemental, common-sense balancing of such competitive rights as may be involved with the requirements for effective medical treatment of patients:

> "The simplest way to reduce illegal substitution and mislabeling is to require that cyclandelate be sold in capsules which do not resemble those used for CYCLOSPASMOL. This would alert the patient to the possibility that he has been given cyclandelate when his doctor specifically prescribed CYCLOSPASMOL, as well as put him on notice that the lower generic cost of the cyclandelate should have been charged if that is in fact what he has received. Such a change could be made by appellees without any appreciable difficulty or expense." *Ives Laboratories, Inc. v. Darby Drug Co.*, 638 F.2d 538, 545 (2nd Cir. 1981).

Various materials before this Court have argued that physicians would refrain from prescribing the Petitioners' products if the Petitioners are required to market their products in colors different from those used by the Respondent.[9] Such assertions have gone so far as to suggest that a physician will prescribe a given brand because of its color. These assertions are unsupported, but represent so astounding a theory of the practice of medicine that the

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9. See, for example, Brief of Petitioner Inwood Laboratories, Inc. 50; Brief of *Amicus Curiae* Generic Pharmaceutical Manufacturers Association 25; and Brief of *Amici Curiae* American Association of Retired Persons and the National Retired Teachers Association 5.

Academy believes they should not go unanswered. While the Academy cannot introduce evidence herein, the Academy, as the largest medical specialty society in the world, states its unequivocal belief that no responsible physician bases his prescription for his patient upon the color of the capsules; that no responsible physician would refrain from prescribing a medicine, or a particular brand thereof, which that physician felt best for his patient merely to conserve the physician's own time; and that physicians have not in fact encountered significant problems in securing patient compliance with prescriptions because of color, but if a patient should question the color of his prescription, the physician would be ready and able to explain the appropriateness of the particular prescription (either brand or generic, as the case might be).

II. The Patient Has the Right to Know and Be Able to Determine Whether His Prescription Has Been Filled With the Brand Name Drug or a Generic Substitute, Not Only As a Matter of Elemental Fairness but Also to Enable Him to Determine Whether He Is Accorded Benefits of Cost Savings Where His Physician Has Permitted Generic Substitutions.

There are several reasons why a patient has the right to know what medicine is being dispensed to him. Most importantly, his basic human right to receive medical treatment certainly contains within it the right to know that the brand of medicine which he receives is that which has been prescribed for him, or at the least to know if there is any difference. The essential reason for this right of the patient is to ensure that the patient receives the medical treatment his physician intended, as discussed in the preceding section of this brief.

Drug substitution laws have been developed for a further purpose which is intended to be beneficial to the patient. The general purpose of such laws is to secure cost savings which, in the ideal situation, will be passed on to the consumer. The Academy is in full and indeed active accord with the goal of reducing the cost to patients of medical treatment. The Academy sponsors, co-sponsors or otherwise supports numerous study and research projects each year the goal of which is to find ways of reducing costs of medical care without unsatisfactorily reducing the quality of that care. As previously noted herein, official Academy policy adopted in 1967 referred specifically to the propriety of a generic prescription where appropriate to a patient's medical condition.[10]

Obviously, however, if a patient can be fooled into believing that he has received a higher priced product because the capsules dispensed to him look just like the higher priced product, the patient becomes a very easy mark for the unscrupulous pharmacist (and indeed simply for the inadvertent pharmacist who may also be misled by the similarity in appearance into making innocent mistakes). Such a patient may be denied the cost savings to which he is entitled without ever knowing the difference.

The Petitioners' argument that the color of the capsule somehow performs a "function" rests at bottom on the goal of deceiving the patient. In essence, Petitioners argue that if a patient knows he is not getting the brand of medicine prescribed for him, he may develop anxiety. Petitioners' "cure" for such anxiety is to use similar colors so that a substituted brand will look just like the prescribed one. Thus the patient will think he is getting a product

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10. American Academy of Family Physicians, *1981-1982 Ready Reference Guide, Academy Policy on Key Health Issues* 16 (1981)

he really is not getting and, in his blissful ignorance, he will not develop anxiety. Wholly apart from the medical dangers and indeed the sheer arrogance of such an argument, the immediate point is that a patient receiving such a substitution, of which he is deliberately kept unknowing so that he will not develop "anxiety," will by that reason not know to complain when he is charged full price for the substituted product.

It is not necessary to hypothesize most pharmacists as dishonest or careless in order to condemn the conditions that make such results possible. The record in this case contains ample instances where improper substitutions have been discovered to show that the possibility of such substitutions is not merely a figment of an active imagination. Whether such results have occurred honestly or dishonestly, their net result to the patient is the same: not only is the patient exposed to the risk of improper medical treatment, but he may also be denied the financial benefits which the drug substitution laws were supposed to obtain for him.

The courts below have provided a practical answer. Judge Friendly, on the original appeal to the Second Circuit, noted that "an endless number of color combinations was available to the defendants." *Ives Laboratories, Inc. v. Darby Drug Co.*, 601 F.2d 631, 643 (2nd Cir. 1979). Judge Mansfield, writing for the Court of Appeals the opinion with respect to which this writ was granted, noted that by simply using capsules which did not resemble those used by the Respondents, the Petitioners could, "without any appreciable difficulty or expense" put a patient "on notice that the lower generic cost of the cyclandelate should have been charged if that is in fact what he has received." *Ives Laboratories, Inc. v. Darby Drug Co.*, 638 F.2d 538, 545 (2nd Cir. 1981).

CONCLUSION

The Academy has been organized and exists for the primary purpose of enhancing the quality of medical care. It is concerned whenever practices are encouraged which endanger the adequacy of medical treatment. For the reasons stated, the Academy believes that permitting different products intended for a given medical condition to be unnecessarily similar in appearance creates the possibility of deficiencies in medical treatment and in some circumstances endangers the patient's welfare. Therefore, the Academy respectfully requests that the judgment of the Court of Appeals herein be affirmed.

Respectfully submitted,

GERALD W. GORMAN
(Counsel of Record)
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1700 City Center Square
1100 Main Street
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(816) 221-3420
Attorneys for American Academy of Family Physicians

Of Counsel:
CAROL A. WESTRICH

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of December, 1981, three copies of the Brief of *Amicus Curiae* American Academy of Family Physicians In Support of Respondent were served by United States mail with first-class postage prepaid on each of the following:

1. Marie V. Driscoll, Esquire
   Cooper, Dunham, Clark, Griffin & Moran
   Attorneys for Respondent Ives Laboratories, Inc.
   30 Rockefeller Plaza
   New York, New York 10112

2. Robert V. Marrow, Esquire
   Salon, Marrow, Dyckman & Kellman
   Attorneys for Petitioners Darby Drug Co., Inc., MD Pharmaceutical Company, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Co., Inc.
   41 East 42nd Street
   New York, New York 10017

3. Milton A. Bass, Esquire
   Bass, Ullman & Lustigman
   Attorneys for Petitioner Inwood Laboratories, Inc.
   747 Third Avenue
   New York, New York 10017

4. Peter T. Cobrin, Esquire
   Kirschstein, Kirschstein, Ottinger & Cobrin, P.C.
   Attorneys for Petitioner Premo Pharmaceutical Laboratories, Inc.
   666 Fifth Avenue
   New York, New York 10103

I further certify that all parties required to be served have been served.

/s/ GERALD W. GORMAN
GERALD W. GORMAN
(Counsel of Record)
DIETRICH, DAVIS, DICUS, ROWLANDS
& SCHMITT
1700 City Center Square
1100 Main Street
Kansas City, Missouri 64105
(816) 221-3420
Attorneys for American Academy of Family Physicians

EXHIBIT A

[Letterhead of Cooper, Dunham,
Clark, Griffin & Moran]

November 27, 1981

Gerald W. Gorman, Esq.
Dietrich, Davis, Dicus, Rowlands & Schmitt
1700 City Center Square
1100 Main Street
Kansas City, Missouri 64105

Re: Inwood Laboratories, Inc. et al v. Ives
Laboratories, Inc. and
Darby Drug Co., Inc. et al v. Ives
Laboratories, Inc.
Nos. 80-2182 and 81-11

Dear Gerald:

This is to confirm that Respondent, Ives Laboratories, Inc. consents to the filing of a brief amicus curiae in this case by the American Academy of Family Physicians.

Sincerely yours,

/s/ Marie Driscoll
Marie V. Driscoll
Attorney for Respondent

MVD:jt

EXHIBIT B-1

[Letterhead of Dietrich, Davis,
Dicus, Rowlands & Schmitt]

December 3, 1981

Mr. Milton A. Bass, Esquire
Bass, Ullman & Lustigman
747 Third Avenue
New York, New York 10017

Re: Darby Drug Company, Inc., Inwood Laboratories, Incorporated, MD Pharmaceutical Company, Inc., Premo Pharmaceutical Laboratories, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Company, Inc. vs. Ives Laboratories, Inc.

Dear Mr. Bass:

In accordance with Rule 36 of the Rules of the Supreme Court of the United States, we respectfully request your written consent to our filing of a brief amicus curiae in the above-captioned matter on behalf of the American Academy of Family Physicians.

Please acknowledge your consent by signing this letter at the space indicated below and returning the same via the enclosed addressed envelope.

We appreciate your cooperation in this matter.

Very truly yours,

/s/ Gerald W. Gorman
Gerald W. Gorman

GWG:cle

Petitioner Inwood Laboratories, Inc. consents to the filing of the brief amicus curiae in the captioned matter on behalf of the American Academy of Family Physicians.

DATE: 12/7/81

/s/ Milton A. Bass
Milton A. Bass, Esquire
Attorney for Petitioner
Inwood Laboratories, Inc.

EXHIBIT B-2

[Letterhead of Dietrich, Davis,
Dicus, Rowlands & Schmitt]

December 3, 1981

Mr. Peter T. Cobrin, Esquire
Kirschstein, Kirschstein, Ottinger & Cobrin, P.C.
666 Fifth Avenue
New York, New York 10103

Re: Darby Drug Company, Inc., Inwood Laboratories, Incorporated, MD Pharmaceutical Company, Inc., Premo Pharmaceutical Laboratories, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Company, Inc. vs. Ives Laboratories, Inc.

Dear Mr. Cobrin:

In accordance with Rule 36 of the Rules of the Supreme Court of the United States, we respectfully request your written consent to our filing of a brief amicus curiae in the above-captioned matter on behalf of the American Academy of Family Physicians.

Please acknowledge your consent by signing this letter at the space indicated below and returning the same via the enclosed addressed envelope.

We appreciate your cooperation in this matter.

Very truly yours,

/s/ Gerald W. Gorman
Gerald W. Gorman

GWG:cle

Petitioner Premo Pharmaceutical Laboratories, Inc. consents to the filing of the brief amicus curiae in the captioned matter on behalf of the American Academy of Family Physicians.

Date: 12/8/81

/s/ Peter T. Cobrin
Peter T. Cobrin, Esquire
Attorney for Petitioner Premo
Pharmaceutical Laboratories,
Inc.

EXHIBIT B-3

[Letterhead of Dietrich, Davis,
Dicus, Rowlands & Schmitt]

December 3, 1981

Mr. Robert V. Marrow, Esquire
Salon, Marrow, Dyckman & Kellman
41 East 42nd Street
New York, New York 10017

Re: Darby Drug Company, Inc., Inwood Laboratories, Incorporated, MD Pharmaceutical Company, Inc., Premo Pharmaceutical Laboratories, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Company, Inc. vs. Ives Laboratories, Inc.

Dear Mr. Marrow:

In accordance with Rule 36 of the Rules of the Supreme Court of the United States, we respectfully request your written consent to our filing of a brief amicus curiae in the above-captioned matter on behalf of the American Academy of Family Physicians.

Please acknowledge your consent by signing this letter at the space indicated below and returning the same via the enclosed addressed envelope.

We appreciate your cooperation in this matter.

Very truly yours,

/s/ Gerald W. Gorman
Gerald W. Gorman

GWG:cle

Petitioners Darby Drug Company, Inc., MD Pharmaceutical Company, Inc., Rugby Laboratories, Inc. and Sherry Pharmaceutical Company, Inc. consent to the filing of the brief amicus curiae in the captioned matter on behalf of the American Academy of Family Physicians.

Date: 12/8/81

/s/ Robert V. Marrow
Robert V. Marrow, Esquire
Attorney for Petitioners.